K082594

510(k) Summary

Submitter Name: Submitter Address:	Remedent NV Xavier de Cocklaan 42 Deurle, BELGIUM B-9831
Phone Number: Fax Number:	603 369 3550 603 369 3562
Contact Person:	William Greenrose
Date Prepared:	02 September 2008
Device Trade Name:	Remesense
Common Name	Tooth Desensitizer
Classification Name, Number & Product Code:	Cavity Varnish 872.5260 LBH
Predicate Devices:	K061438 - UltraEZ, K041680 - Orajel, K983477 - SuperSeal, K073061 - Provident (details in table below)
Device Description and Statement of Intended Use	Device Description: Remesense consists of a tray and impregnated foam strips. The Remesense foam strips are thin flexible foam strips, impregnated with a desensitizing liquid. These strips are designed to relieve dental (hyper) sensitivity by patient application to the affected tooth (teeth). The impregnated foam strips are held in place with trays. Statement of Intended Use: Remesense is intended for the local management of dental sensitivity by patient application of foam strips impregnated with desensitizing gel.
Summary of Technological Characteristics	Potassium oxalate breaks down into potassium and oxalic acid. The oxalic acid reacts with calcium ions to form calcium-oxalate crystals. These crystals block the dentin tubules, thereby alleviating dental sensitivity. Blockage of dentin tubules is commonly used by many tooth sensitivity agents to reduce tooth sensitivity, and potassium oxalate is a common material used to block dentin tubules.

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Conclusion

The information discussed above demonstrates that the Remesense device is substantially equivalent to the predicate devices

Declarations

- This summary includes only information that is also covered in the body of the 510(k).
- This summary does not contain any puffery or unsubstantiated labeling claims.
- This summary does not contain any raw data, i.e., contains only summary data.
- This summary does not contain any trade secret or confidential commercial information.
- This summary does not contain any patient identification information.

Summary of Technical Characteristics

Feature	Remesense	UltraEZ	Orajel	Superseal	Provident
510(k) Number	TBD	K061438	K041680	K983477	K073061
Manufacturer	Remedent	Ultradent Products, Inc.	DEL Pharmaceuticals, Inc.	Phoenix Dental, Inc.	Coll Partners, Ltd.
Classification # & Product Code	**872.3260 LBH**	**872.3260 LBH**	872.3200 KLE	872.3250 EJK	**872.3260 LBH**
Classification Name	Cavity Varnish	Cavity Varnish	Tooth bonding resin agent	Calcium hydroxide cavity liner	Cavity Varnish
Common Name	**Tooth Desensitizer**	**Tooth Desensitizer**	**Tooth Desensitizer**	**Tooth Desensitizer**	**Tooth Desensitizer**
Indications for Use	**Tooth Desensitizer**	Provides a film like varnish for exposed teeth sealing dentinal tubules of over exposed dentin or other exposed areas where postoperative or other dentin sensitivity is a concern.	**Tooth Desensitizer**	A potassium oxalate based film forming acid resistant liner and desensitizer that is indicated for application prior to restoration of exposed dentin.	A fluoride containing varnish system intended for use as a desensitizing agent on the surface areas of hypersensitive or potentially sensitive teeth.
Mode of Action	**Tubule Occlusion**	**Tubule Occlusion**	**Tubule Occlusion**	**Tubule Occlusion**	**Tubule Occlusion**
Material Composition	**Potassium Oxalate**	KNO3 and KF	2-hydroxyethyl methacrylate	**Potassium Oxalate**	KF
Application	**Tray/Kit/Gel**	**Gel**	Liquid w/Swab	**Gel**	**Tray/Kit/Gel**
Rx/OTC	**Rx**	**Rx**	**Rx**	**Rx**	**Rx**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2009

Remedent NV
C/o Mr. William Greenrose
President
Qserve America, Incorporated
220 River Road
Claremont, New Hampshire 03743-5567

Re: K082594
Trade/Device Name: Remesense
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: March 12, 2009
Received: March 17, 2009

Dear Mr. Greenrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

for Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.1 Indications for Use Statement

510(k) Number (if known): K082594

Device Name: Remesense

Indications for Use:

Remesense is indicated for use as a tooth desensitizer.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)	X	OR	Over-The-Counter Use	

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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